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EXAMINER	
MUI, CHRISTINE T	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,992	BRENNEMAN, ALLEN J.	
	Examiner	Art Unit	
	CHRISTINE T. MUI	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7-11,13,14,16-22 and 26-28* is/are rejected.

7)☒ Claim(s) *2,5,6,12, 15 and 23-25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05 February 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see REMARKS/ARGUMENT, filed 26 March 2008, with respect to the rejection(s) of claim(s) 1-26 under 35 USC 102(b) and 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of USP 5,525,518 to Lundsgaard et al; USP 5,564,419 to Lundsgaard et al.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 7-9 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,564,419 to Lundsgaard et al. (herein referred 'Lundsgaard').

4. Regarding claims 1, 3, and 7-9, the reference Lundsgaard discloses a method for photometric in vitro determination of the content of oxygen in a blood sample. The blood sample is transferred directly from an in vivo locality to an at least partially transparent sample container of a sample device. The sample container as seen in Figure 8, comprises two halves that are assembled by pins and recesses in the halves where each of the halves have both pins and recesses that engage in each other when assembled. The two halves are welded together by ultrasonic welding. As can be seen in Figure 8, the container has a sample conduit defined in the inner surface of both

halves that centrally expands traversely into a measuring chamber. The two halves are made from plastic and one of the walls of the measuring chamber consists of a glass plate in the form of a microscope cover glass, on which there is cast a 2 micrometer coating of PVC containing PdTFPP. A double adhesive ring secures the plate to the sample part of the container. The sample container may have dimensions sufficiently small for the sample container to be filled by capillary effect (see abstract, column 6,lines 35-37, column 9, line 49-column 10, line 3). It is interpreted by the examiner that the read surfaces are the bottom and top side of the measuring chamber that has a microscope cover glass and a coating. Furthermore, as can be seen in Figure 8, the halves of the sample container are identical to each other.

5. Regarding claim 27, the reference Lundsgaard discloses in an example a solution consisting of 15 mg of PdTFPP, 199.5 mg PVC and 1.5 ml tetrahydrofuran is cast on a rotating microscope cover glass etched by hydrofluoric acid in a dry atmosphere by putting on 10 micro liter solution as drops (see column 10, lines 6-13).

6. Claims 11, 13 and 16-22, 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,525,518 to Lundsgaard et al (herein referred 'Lundsgaard II').

7. Regarding claims 11, 13 and 17-18, the reference Lundsgaard II discloses a method of photometric in vitro determination of at least one blood gas parameter in a sample of whole blood. The whole blood sample is obtained by connecting an at least partially transparent sample container to an in vivo locality and transferring whole blood into the sample container. The sample container as seen in Figure 12, the sample

container consists of two halves that include an internal sample conduit that is defined in both halves of the sample container and which centrally expands traversely for forming a measuring chamber. The two halves are made of plastic material and are welded together by ultrasonic welding, but the measuring chamber is in a direction perpendicular to the conduit, defined by two glass plates or alternatively EVAL-E™ plates secured between the two halves, which are considered to be read windows. One or several very thin lines of material ensure a well defined distance between the two plates. The container halves are made from a transparent plastic material, e.g., softened polymethyl methacrylate of the type DEGLAN™. The two halves are assembled by pins and recesses in one half and pins and recesses in the other half, which engage in each other. The sample of blood is provided by a capillary puncture, the use of the sample container with a dimension sufficiently small for the sample container to be filled by capillary effect (see abstract, column 5, line 66- column 6, line 2, column 10, lines 8-32, column 11, lines 3-39). It can be seen in Figure 12, the measuring chamber that is defined by two glass plates that are secured between the two halves are considered to be aligned with read surfaces of the measuring chamber so that upon radiation, the radiation source can illuminate the sample through the window of the first half all the way through to the other half.

8. Regarding claim 16, the reference Lundsgaard II discloses that a solution consisting of 15 mg PdTFPP, 199.5 mg PVC and 1.5 ml tetrahydrofuran is cast on the microscope cover glass etched by hydrofluoric acid (see column 11, lines 43-50).

9. Regarding claims 19-22 and 26, the reference Lundsgaard II discloses a method of photometric in vitro determination of at least one blood gas parameter in a sample of whole blood. The whole blood sample is obtained by connecting an at least partially transparent sample container to an in vivo locality and transferring whole blood into the sample container. The sample container as seen in Figure 12, the sample container consists of two halves that include an internal sample conduit that is defined in both halves of the sample container and which centrally expands traversely for forming a measuring chamber. The two halves are made of plastic material and are welded together by ultrasonic welding, but the measuring chamber is in a direction perpendicular to the conduit, defined by two glass plates or alternatively EVAL-E™ plates secured between the two halves. One or several very thin lines of material ensure a well defined distance between the two plates. The container halves are made from a transparent plastic material, e.g., softened polymethyl methacrylate of the type DEGLAN™. The two halves are assembled by pins and recesses in one half and pins and recesses in the other half, which engage in each other. The sample of blood is provided by a capillary puncture, the use of the sample container with a dimension sufficiently small for the sample container to be filled by capillary effect (see abstract, column 5, line 66- column 6, line 2, column 10, lines 8-32, column 11, lines 3-39). As can be seen in Figure 12, the measuring chamber that is defined by two glass plates that are secured between the two halves are considered to be aligned with read surfaces of the measuring chamber so that upon radiation, the radiation source can illuminate the sample through the window of the first half all the way through to the other

half. It is interpreted by the examiner that since the sample container in Figure 12 does not mention an adhesive to hold the two halves together and the pins and recesses of the sample container engage in each other when assembled, the inner surfaces of the halves are substantially free of adhesive.

10. Regarding claim 28, the reference Lundsgaard II discloses that a solution consisting of 15 mg PdTFPP, 199.5 mg PVC and 1.5 ml tetrahydrofuran is cast on the microscope cover glass etched by hydrofluoric acid (see column 11, lines 43-50).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundsgaard as applied to claim 1 above, and further in view of Lundsgaard II.

14. Regarding claim 4, the reference Lundsgaard discloses the claimed invention except for where the sample container comprises of optical windows that align on the

read surfaces. Lundsgaard II discloses another method of photometric in vitro determination of at least one blood gas parameter in a sample of whole blood. In sampling, the blood is placed in the a container as seen in Figure 12, the sample container comprises of two halves designed with a measuring chamber that are defined by two glass plates or alternatively EVAL-E™ plates that are secured (see column 11, lines 3-20). It is interpreted by the examiner that the glass plates are optical windows that are aligned with the read surface of the measuring chamber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide optical windows aligned with the read surfaces of the two halves so that the windows may provide protection from contamination and drying of the sample when subjected to the radiation source.

15. Regarding claim 10, the reference Lundsgaard discloses the claimed invention except for where the inner surfaces of the formats are held together being substantially free of adhesive or other intervening material. Lundsgaard discloses the sample container in Figure 12, the two halves are held together when the pin and recesses are engaged in each other without any mention of any adhesive in the sample container and are held together by ultrasonic welding (see column 10, lines 20-21, column 11, lines 3-20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the interfaces of the formats be held together substantially free of adhesive so that upon radiation, the adhesive does not interfere with the sample by creating an unwanted reaction.

Allowable Subject Matter

16. Claims 2, 5-6, 12, 15 and 23-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. A format for the optical analysis of a sample where the format comprises of the pin and holes are joined together with adhesive is not found in the prior art. Furthermore, a first format that has slots disposed on the first and second side of the surfaces and a second format that has slots disposed on the third and fourth side of the surface is not found in the prior art for the purposes of stacking the formats together.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE T. MUI whose telephone number is (571)270-3243. The examiner can normally be reached on Monday-Thursday 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797